

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

SHERISE RICHARDSON, individually and  
on behalf of all others similarly situated,

Plaintiff,

vs.

EDGEWELL PERSONAL CARE, LLC,

Defendant.

Civil Action No. 7:21-cv-08275-PMH

**DEFENDANT EDGEWELL PERSONAL CARE, LLC'S MEMORANDUM OF LAW  
IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S  
FIRST AMENDED CLASS ACTION COMPLAINT**

STINSON LLP

Kieran Corcoran (KC4935)  
Telephone 212.763.8491  
Fax: 917.439.4993  
Email: kieran.corcoran@stinson.com  
1325 Avenue of the Americas, 27<sup>th</sup> Floor  
New York, NY 10019

STINSON LLP

Thomas H. Davis (*admitted pro hac vice*)  
Telephone 816.691.3439  
Fax: 816.412.1100  
Email: thomas.davis@stinson.com  
Megan McCurdy (*admitted pro hac vice*)  
Telephone 816.691.2649  
Fax: 816.412.9733  
Email: megan.mccurdy@stinson.com  
Logan T. Fancher (*admitted pro hac vice*)  
Telephone 816.691.2692  
Fax: 816.412.1132  
Email: logan.fancher@stinson.com  
1201 Walnut, Suite 2900  
Kansas City, MO 64106

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Defendant Edgewell Personal Care, LLC, respectfully submits the following Memorandum of Law in Support of its Motion to Dismiss the Plaintiff Sherise Richardson’s (“Plaintiff”) First Amended Complaint (“FAC”) (ECF 23) pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

### **INTRODUCTION**

Plaintiff alleges that Defendant deceptively and falsely marketed its Hawaiian Tropic® sunscreen products as “Reef Friendly.” *See* ECF 23 at ¶ 2. The full claim on the label at issue, which Plaintiff ignored, reads “Reef Friendly\*” with the back label asterisk further explaining: “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate.” *See e.g.*, ECF 23-1.

The Court should dismiss Plaintiff’s FAC for the following reasons:

*First*, a reasonable consumer does not ignore half the claim on the label and Plaintiff fails to plausibly allege that a significant portion of the general consuming public would be misled by a “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim. *See* ECF 23-1.

*Second*, Plaintiff lacks both Article III and Gen. Bus. Law §§ 349 and 350 statutory standing because she lacks injury-in-fact, failed to plausibly plead price premium, and ignored half the claim on the label.

*Third*, Plaintiff’s warranty claims – along with those of the alleged nationwide class – require dismissal because Plaintiff lacks privity with Defendant, failed to provide the required pre-suit notice, and cannot allege reliance while ignoring half the claim on the label.

*Fourth*, Plaintiff’s claims are subject to the FDA’s primary jurisdiction.

Plaintiff is not entitled to claim that a label is false, misleading, and deceptive while simultaneously ignoring half of what that label says: “A plaintiff who alleges that he was deceived by an advertisement may not misquote or misleadingly excerpt the language of the advertisement in his pleadings and expect his action to survive a motion to dismiss or, indeed, to escape admonishment.” *Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013) (affirming dismissal of NY GBL § 349 claim). *See* ECF 23 at ¶¶ 2-3. Plaintiff filed her FAC alleging violations of New York’s Gen. Bus. Law § 349 (Count I), New York’s Gen. Bus. Law § 350 (Count II), and breach of express and implied warranties (Count III).

Plaintiff alleges that Defendant “falsely, misleadingly, and deceptively” labels its Hawaiian Tropic® sunscreen products as “Reef Friendly.” ECF 23 at ¶ 3. Plaintiff states that she and similarly situated consumers “would not have purchased the Products, or would not have purchased the Products for as great a price, if they had known that the [“Reef Friendly” claim on the label] was false[.]” *Id.* at ¶ 44. Plaintiff, however, fails to address the fact that the “Reef Friendly\*” claim includes an asterisk, which leads consumers to explanatory language at the top of the back label informing consumers what “Reef Friendly\*” means: “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate.” In her original Complaint, Plaintiff did not mention the explanatory language at all nor did Plaintiff include full and complete images of the products’ labels with her Complaint. *See* ECF 1. For the first time in her FAC, Plaintiff admits she did not read the explanatory “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” language, which of course constitutes half of the “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim on the label. *See* ECF 23, ¶ 9. Additionally, alongside her FAC Plaintiff filed

the full images of the products' labels. *See* ECF 23-1. Regardless of whether Plaintiff read it or not, the explanatory language is on the products' labels for all consumers to see. *See* ECF 23-1.

Plaintiff alleges the labels are false or misleading, but also admits that she failed to read what the labels actually say. This fundamental failure alone warrants dismissal for multiple reasons, not to mention additional, fatal defects.

## **ARGUMENT**

### **I. LEGAL STANDARD.**

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). “A pleading that offers labels and conclusions or a formulaic recitation of the elements” or “tenders naked assertion[s] devoid of further factual enhancement” will not suffice. *Id.* A claim has facial plausibility only “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* The plausibility standard requires “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* The factual allegations pleaded “must be enough to raise a right to relief above the speculative level.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

### **II. PLAINTIFF FAILS TO MEET THE REASONABLE CONSUMER STANDARD.**

Plaintiff does not—and cannot—plausibly allege that a significant portion of the general consuming public would be misled by Defendant’s “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim on the label. Accordingly, Plaintiff’s claims should be dismissed because they fail to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6).



Under either GBL § 349 or § 350, a plaintiff must demonstrate that “a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice.” *Kommer v. Bayer Consumer Health*, 252 F. Supp. 3d 304, 310–11 (S.D.N.Y. 2017), *aff’d sub nom. Kommer v. Bayer Consumer Health, a division of Bayer AG*, 710 F. App’x 43 (2d Cir. 2018) (citing *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015)). “Section 349 of the GBL declares deceptive acts and practices unlawful and section 350 declares false advertising unlawful. ‘The standard for recovery under [section] 350, while specific to false advertising, is otherwise identical to Section 349.’” *Barreto v. Westbrae Nat., Inc.*, 518 F. Supp. 3d 795, 802 (S.D.N.Y. 2021) (quoting *Denenberg v. Rosen*, 71 A.D.3d 187, 194, 897 N.Y.S.2d 391 (1st Dep’t 2010)). “Conduct is materially misleading under GBL §§ 349 and 350 if it is ‘likely to mislead a reasonable consumer acting reasonably under the circumstances.’” *Id.* (quoting *Oswego Laborers’ Loc. 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 26, 647 N.E.2d 741 (1995)).

This inquiry is objective and “may be resolved as a matter of law on a motion to dismiss.” *Kommer*, 252 F. Supp. 3d. at 311. *See also Fink*, 714 F.3d at 741 (“It is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer.”); *S.Q.K.F.C., Inc. v. Bell Atl. TriCon Leasing Corp.*, 84 F.3d 629, 637 (2d Cir. 1996). Accordingly, “plaintiffs must do more than plausibly allege that a label might conceivably be misunderstood by some few consumers. Plaintiffs must plausibly allege that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.” *Jessani v. Monini N. Am., Inc.*, 744 F. App’x 18, 19 (2d Cir. 2018) (internal citations and quotations omitted).

**A. A Significant Portion of the General Consuming Public Would Not Be Misled by “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate.”**

Unlike Plaintiff, the general consuming public would not ignore half of what the “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim on the label says. Reasonable consumers are required to read the product’s label. *See Gordon v. Target Corp.*, 20-CV-9589, 2022 WL836773, \*10 (S.D.N.Y. Mar. 18, 2022) (“[i]t is unreasonable—as Plaintiff attempts—to suggest that a consumer is not required to read a product’s label to obtain information.”) (quoting *Devane v. L’Oreal USA, Inc.*, No. 19 CIV. 4362 (GBD), 2020 WL 5518484, at \*5, n. 3 (S.D.N.Y. Sept. 14, 2020)).

Where, as here, a plaintiff’s claims are predicated on an alleged misrepresentation on a product package, those claims should be dismissed if the product packaging and labels *as a whole* are not plausibly “likely to mislead a reasonable consumer acting reasonably under the circumstances.” *Kommer*, 252 F. Supp. 3d at 310–11. *See also Barreto*, 518 F. Supp. 3d at 802 (“In determining whether a reasonable consumer would be misled, ‘[c]ourts view each allegedly misleading statement in light of its context on the product label or advertisement as a whole.’”) (quoting *Pichardo v. Only What You Need, Inc.*, No. 20-CV-493 (VEC), 2020 WL 6323775, at \*2 (S.D.N.Y. Oct. 27, 2020)); *Belfiore v. Procter & Gamble Co.*, 311 F.R.D. 29, 53 (E.D.N.Y. 2015) (“Courts view each allegedly misleading statement in light of its context on the product label or advertisement as a whole. The entire mosaic is viewed rather than each tile separately.” (internal quotation marks omitted)); *Time Warner Cable, Inc. v. DIRECTV, Inc.*, No. 06 Civ. 14245, 2007 WL 1138879, at \*4 (S.D.N.Y. April 16, 2007) (“In considering false advertising claims, the Court is to bear in mind that ‘fundamental to any task of interpretation is the principle that text must yield to context,’ and that the Court must ‘consider the advertisement[s] in [their] entirety and not engage in disputatious dissection.’”) (quoting *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238

(2d Cir. 2001)). Plausibility in this context requires “more than a sheer possibility that a defendant acted unlawfully” and considers “the full factual picture presented by the complaint, the particular cause of action and its elements, and the existence of alternative explanations so obvious that they render plaintiff’s inferences unreasonable.” *Fink*, 714 F.3d at 742. Accordingly, “[t]he presence of a disclaimer or similar clarifying language may defeat a claim of deception.” *Fink*, 714 F.3d at 742. *See also Chiste v. Hotels.com L.P.*, 756 F. Supp. 2d 382, 404 (S.D.N.Y. 2010) (“There can be no claim for deceptive acts or practices, however, when the alleged deceptive practice was fully disclosed.”); *Kommer v. Bayer Consumer Health*, 252 F.Supp.3d 304, 312 (S.D.N.Y. 2017) (dismissing claims where a “disclaimer [was] printed in reasonably-sized font right at the top of the Instructions” that were allegedly deceptive), *aff’d sub nom. Kommer v. Bayer Consumer Health, a division of Bayer AG*, 710 F. App’x 43, 44 (2d Cir. 2018).

It is indisputable that the very same label on the product that contains the “Reef Friendly\*” statement that Plaintiff complains about *also* includes explanatory language telling consumers *exactly* what “Reef Friendly\*” means: “\*Hawaii Compliant – No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate.” *See* ECF 23-1. It is further indisputable that the “Reef Friendly\*” statement on each of the products is followed immediately by an asterisk. *See* ECF 23 at ¶ 2. A significant portion of the general consuming public would not look at “Reef Friendly\*,” with an asterisk, and believe it is a complete representation: a reasonable consumer knows that an asterisk indicates there is more they need to read. *See e.g., Turk v. Rubbermaid Inc.*, No. 21-CV-270 (KMK), 2022 WL 836894, at \*7 (S.D.N.Y. Mar. 21, 2022) (dismissing Section 349 and 350 claims where the alleged misleading statement was “accompanied by an asterisk leading to another statement” that qualified it, reasoning “[t]he Court fails to understand how a reasonable consumer

could interpret those statements to mean [what Plaintiff alleged].”).<sup>1</sup> A reasonable consumer will read the full representation, including the explanatory language following the asterisk, and know what the term “Reef Friendly\*” means. *See Gordon*, 2022 WL836773, \*10.

Plaintiff alleges that Defendant misled reasonable consumers, including Plaintiff, into believing that the products only contain ingredients that cannot harm or kill coral reefs. *See ECF 23 at ¶ 3*. But Defendant makes no such representation. Plaintiff’s faux definition of “Reef Friendly\*” is facially inconsistent with the explanatory language following the asterisk. The definition of “Reef Friendly\*” is included on the label: “\*Hawaii Compliant – No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate.” Plaintiff is not entitled to ignore the definition on the label, substitute her own strategically concocted definition in its place and allege that the label is deceptive or misleading.

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<sup>1</sup> Both New York and California apply a “reasonable consumer” standard to consumer fraud claims. *See Fink*, 714 F.3d at 741 (“To prevail on their consumer fraud claims under New York and California law, Plaintiffs must establish that [Defendant]’s allegedly deceptive advertisements were likely to mislead a reasonable consumer acting reasonably under the circumstances.”). Yet even in California, arguably the most favorable jurisdiction in the country for alleging a false or deceptive advertising claim, courts dismiss claims like Plaintiff’s because reasonable consumers know what an asterisk means on product labels:

Asterisks are common in both commerce and elsewhere to denote that the ‘reader’ should be aware that there is more than meets the eye. Because the asterisk calls the consumer’s attention to the fact that there is supplemental information on the package that the consumer should read, it matters less that the disclosure is allegedly not conspicuous on the package. Once the consumer is directed to look for the disclosure because of the asterisk, he knows to look for it and can find it in the fine print.

*Dinan v. SanDisk LLC*, No. 18-CV-05420-BLF, 2020 WL 364277 (N.D. Cal. Jan. 22, 2020), *aff’d*, 844 F. App’x 978 (9th Cir. 2021); *Garcia v. Sony Computer Ent. Am., LLC*, 859 F. Supp. 2d 1056 (N.D. Cal. 2012) (statements on package about product compatibility accompanied by an asterisk directing consumers to a separate document were “only partial statements, and do not rise to the level of affirmative misrepresentations” without examining the document referred to).

Plaintiff's omission is fatal under New York law. *See Gordon v. Target Corp.*, 20-CV-9589, 2022 WL836773, \*10 (S.D.N.Y. Mar. 18, 2022) (dismissing claims under GBL §§ 349 and 350 because the plaintiff "failed to actually identify a material misstatement or omission on the Product's label that would deceive a reasonable consumer.). In *Gordon*, the court analyzed a claim that a product's label misleadingly concealed the existence of added sugar – despite the disclosure of added sugar on the product's label. *Id.* at \*11. The court reasoned that it must consider "each allegedly misleading statement in light of its context on the product label or advertisement as a whole" and that the court must review "the entire mosaic...rather than each tile separately." *Id.* The court went on to note that because the label actually did disclose the existence of added sugar, the plaintiff was essentially suggesting that she was "not required to read a product's label to obtain information." *Id.* But "it is unreasonable [to do so]. Reasonableness cannot be based solely on what the consumer might have known prior to picking up the Product[] and examining the label[]." *Id.* (quoting *Devane v. L'Oreal USA, Inc.*, No. 19 CIV. 4362 (GBD), 2020 WL 5518484, at \*5, n. 3 (S.D.N.Y. Sept. 14, 2020)). As such, the court dismissed Plaintiff's claims for failure to establish misrepresentation. *Id.*

The same result should occur here. When read as a whole, the label confirms to a reasonable consumer that "Reef Friendly\*" means "\*Hawaii Compliant – No Oxybenzone or Octinoxate" or "\*No Oxybenzone or Octinoxate" – a true, accurate and supported representation. *Plaintiff nowhere alleges that she was confused by the explanatory language, or that a reasonable consumer would not identify and understand it. See Kommer*, 252 F. Supp. 3d at 312 ("Assuming that a reasonable consumer might ignore the evidence plainly before him 'attributes to consumers a level of stupidity that the Court cannot countenance and that is not actionable under G.B.L. § 349.'" (quoting *Chiste*, 756 F. Supp. 2d at 404)); *Weinstein v. eBay, Inc.*, 819 F. Supp. 2d 219, 228

(S.D.N.Y. 2011) (“[T]he applicable legal standard is whether a reasonable consumer, not the least sophisticated consumer, would be misled by Defendants’ actions.”).

Indeed, Plaintiff admits she never read the explanatory language at all. ECF 23 at ¶ 9. Plaintiff effectively admits that *she is not a reasonable consumer*. As recognized by the Court of Appeals for the Second Circuit, “[a] plaintiff who alleges that [she] was deceived by an advertisement may not misquote or misleadingly excerpt the language of the advertisement in [her] pleadings and expect [her] action to survive a motion to dismiss or, indeed, to escape admonishment.” *Fink*, 714 F.3d at 742. Like the Court of Appeals for the Second Circuit, this Court should “easily conclude that Plaintiff[’s] claims lack the facial plausibility necessary to survive a motion to dismiss.” *See id.*

**B. A Reasonable Consumer Who Never Intended to Use the Product Near Any Coral Reefs Could Not Be Misled.**

Consumers use sunscreen for a variety of purposes, *e.g.*, to go hiking, to mow the lawn, to swim in a swimming pool, and, potentially, to swim in an ocean near coral reefs. The reasonable consumer standard under New York law requires that a purported misrepresentation be one that is “likely to mislead a reasonable consumer acting reasonably *under the circumstances*.” *Daniel v. Mondelez Int’l, Inc.*, 287 F. Supp. 3d 177, 189–90 (E.D.N.Y. 2018) (emphasis in original). Plaintiff never alleges why she purchased the product(s), *i.e.*, whether she intended to swim near coral reefs or whether she purchased sunscreen for some other purpose. Plaintiff merely alleges that she relied on the “Reef Friendly\*” language when she purchased the product(s). ECF 23, ¶ 9. Perhaps Plaintiff intended to swim near a coral reef, perhaps not. Regardless, the applicable standard is not whether *Plaintiff* might be misled by “Reef Friendly\*” language. The applicable standard is whether *a reasonable consumer* would be misled by “Reef Friendly\*” language, even if that reasonable consumer had no intention of using the product(s) in the ocean near any coral reefs.

Plaintiff offers no allegation as to how or why a reasonable consumer could be misled by a “Reef Friendly\*” “\*Hawaii Compliant – No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim if that consumer had no intention of using the product near any coral reefs. Common sense demands that a significant portion of the general consuming public, without the intention to use the product near coral reefs, would not be misled by the “Reef Friendly\*” “\*Hawaii Compliant – No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim on the sunscreen’s label. Plaintiff’s claims should be dismissed.

**C. Plaintiff Fails to Plausibly Allege Defendant Knew the Ingredients Are Harmful to Reefs.**

Plaintiff’s GBL §§ 349 and 350 claims should separately be dismissed because Plaintiff fails to adequately allege that Defendant knew the purportedly “harmful ingredients” are harmful to reefs. A defendant’s failure to disclose information can support a GBL §§ 349 or 350 claim when it exclusively possesses information that a reasonable consumer would want to know and fails to disclose that information. *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 125 (E.D.N.Y. 2011) (“[C]ourts have also imposed this duty on a manufacturer who has exclusive knowledge of a product defect or danger.”) (collecting cases). However, a plaintiff’s complaint must contain sufficient factual specificity to plausibly establish that defendant knew of the undisclosed information in question. *Quintana v. B. Braun Med. Inc.*, No. 17-cv-06614-ALC, 2018 WL 3559091, at \*10 (S.D.N.Y. July 24, 2018) (dismissing GBL §§ 349 and 350 claims where plaintiff merely alleged that defendants “represented on their website and in their brochure that the Filter was safe for its intended use” and that defendant “knew the falsity of their representations about the Filter’s safety” without alleging facts “[suggesting] Plaintiff ever saw these statements and under what circumstances.”); *Woods v. Maytag Co.*, No. 10-cv-0559-ADS-WDW, 2010 WL 4314313, at \*15-16, (E.D.N.Y. Nov. 2, 2010) (dismissing GBL § 349 claim because plaintiff had

“not provided enough factual information to plausibly suggest that the Maytag Defendants had knowledge of the defect” when plaintiff had only “vaguely [alleged] that Defendants ‘knew’ of the alleged defect.”); *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 100 (S.D.N.Y. 1997) (dismissing GBL claims premised on a failure to disclose information because plaintiff’s allegations were “mere conclusions” that “lacked specificity.”).

Thus, Plaintiff must plead specific facts that plausibly establish that defendant knew the ingredients Plaintiff complains about—avobenzone, homosalate, octisalate, and octocrylene—are harmful to reefs. Here, however, Plaintiff’s single allegation on this critical point is buried in ¶ 43 of the FAC: “Defendant is and was, at all times, statutorily required to ensure it has adequate substantiation for the Challenged Representation prior to labeling the Products, advertising the Products, and selling the Products anywhere in the United States. Here, adequate substantiation and compliance with regulatory law require reliable scientific evidence that supports such far-reaching environmentally-friendly and/or eco-friendly claims as the Challenged Representation.” Plaintiff fails to allege how Defendant could possibly know that of avobenzone, homosalate, octisalate, and octocrylene are harmful to reefs when even regulatory agencies like the FDA are still studying the ingredients. *See infra* Section V. The most Plaintiff does is cast vague aspersions about what Defendant might have known or what, in Plaintiff’s subjective view, Defendant should have known. The complete absence of any specific facts regarding Defendant’s knowledge is fatal to Plaintiff’s GBL claims, which requires specific factual allegations that plausibly establish that Defendant was aware the ingredients in the products harm reefs.



### III. PLAINTIFF LACKS STANDING REQUIRING DISMISSAL.

#### A. Plaintiff Lacks Article III Standing Because She Has Not Sustained an Injury in Fact.

Plaintiff's claims should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) because Plaintiff lacks standing. Article III of the United States Constitution dictates that jurisdiction of the federal courts extends only to actual cases or controversies. U.S. Const. art. III. *See also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 590 (1992). To satisfy standing under Article III of the U.S. Constitution, a plaintiff must to show: (1) an injury-in-fact; (2) that the injury is traceable to the challenged action of the defendant; and (3) that the injury is redressable by a favorable ruling. *Lujan*, 504 U.S. at 560–61. *See also Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010); *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000). “A plaintiff seeking to represent a class must personally establish standing for the lawsuit to proceed.” *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016) (citing *Lewis v. Casey*, 518 U.S. 343, 357 (1996)).

The Supreme Court has held that a plaintiff must suffer an injury that is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Lujan*, 504 U.S. at 560; *Spokeo, Inc. v. Robins*, 578 U.S. 330 (2016), *as revised* (May 24, 2016); *Friends of the Earth, Inc.*, 528 U.S. at 180. As the Supreme Court recently noted, a person must have a “concrete injury” beyond a mere statutory violation to have standing. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2205 (2021) (“[U]nder Article III, an injury in law is not an injury in fact. Only those plaintiffs who have been *concretely harmed* by a defendant’s statutory violation may sue that private defendant over that violation in federal court.”) (emphasis in original). “No concrete harm, no standing.” *Id.* at 2214.

Here, Plaintiff has no concrete injury because she fails to allege that she used or intended to use any of the Hawaiian Tropic® sunscreen products—which she claims deceptively include ingredients harmful to coral reefs—near any actual coral reefs. *See* ECF 23. A consumer who does not use and does not plan to use the product(s) near any coral reefs does not suffer a “concrete harm” compared to a consumer who buys the product(s) with the express intention of using it in proximity to a coral reef. Plaintiff fails to allege that she even intended to use any one of the products in the ocean, as opposed to while hiking, swimming in a swimming pool, etc., or that she did not receive the full benefit of the product as a sunscreen to protect her from harmful rays from the sun. *See id.*

Thus, regardless of whether Defendant’s “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim runs afoul of certain statutes—which it does not—Plaintiff herself must have some concrete harm beyond a mere theoretical statutory violation. She has no such concrete harm; thus she has no standing.

**B. Plaintiff Lacks Statutory Standing Under GBL §§ 349 and 350 Because Plaintiff Does Not Plead a Cognizable Injury**

Under either Section 349 or Section 350, a plaintiff must show that a defendant engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice. *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015). Whether a plaintiff has properly alleged an injury for GBL §§ 349 and 350 claims requires a separate inquiry from Article III standing. *Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 576 (S.D.N.Y. 2021). Additionally, “[a] pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action will not do.’ Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’”

*Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 557 (2007)).

To have a cognizable injury under GBL §§ 349 and 350 a plaintiff must prove that “a material[ly] deceptive act or practice caused actual, although not necessarily pecuniary, harm.” *Small v. Lorillard Tobacco Co.*, 94 N.Y.2d 43, 720 N.E.2d 892, 897 (1999). It is well-settled that a plaintiff whose only claimed injury is that she purchased a product “that [she] would not have purchased, absent the manufacturer’s deceptive commercial business practices,” has not suffered an injury under the statutes. *Id.* at 898. In *Small*, for example, the plaintiffs alleged that had the defendants disclosed that nicotine was addictive, they would not have purchased cigarettes. *Id.* The New York Court of Appeals dismissed their claims, holding that plaintiffs’ “flawed ‘deception as injury’ theory” failed to demonstrate that they were “actually harmed or suffered pecuniary injury by reason of any alleged deception within the meaning of the statute.” *Id.* (internal quotes omitted). See also *Irvine v. Kate Spade & Co.*, No. 16-CV-7300 (JMF), 2017 WL 4326538, at \*4 (S.D.N.Y. Sept. 28, 2017) (“Plaintiffs’ first theory—either that they ‘would not have made their purchases,’ or that they ‘would have paid less than they did,’ but for Kate Spade’s allegedly deceptive pricing practices—plainly falls short.”) (internal citation omitted); *Baron v. Pfizer, Inc.*, 42 A.D.3d 627, 629, 840 N.Y.S.2d 445 (3rd Dep’t 2007) (“Without further allegations that, for example, the price of the product was inflated as a result of defendant’s deception or that use of the product adversely affected plaintiff’s health, plaintiff’s claim sets forth deception as both act and injury and, thus, contains no manifestation of either pecuniary or actual harm”); *Donahue v. Ferolito, Vultaggio & Sons*, 13 A.D.3d 77, 786 N.Y.S.2d 153, 154 (1st Dep’t 2004) (holding that trial court properly dismissed claims under §§ 349 and 350 where plaintiffs “impermissibly set up the deception as both act and injury” by alleging that they bought beverages because the labels

promised health benefits, but plaintiffs received no such health benefits, because plaintiffs “never alleged [] that the cost of the beverages was inflated by these misrepresentations or that their health was adversely affected by drinking the beverages.”).

This Court in *Zottola v. Eisai Inc.* applied the very same standard to hold: “[u]nder New York law, a plaintiff’s allegation that he or she bought a product that he or she ‘would not have purchased, absent a manufacturer’s deceptive commercial practices’ is insufficient to establish a cognizable injury under [GBL §§ 349 and 350]. Therefore, Plaintiff’s theory of injury here is a nonstarter.” *Zottola v. Eisai Inc.*, No. 20-CV-02600 (PMH), 2021 WL 4460563, at \*3 (S.D.N.Y. Sept. 29, 2021) (internal citations omitted). This Court further noted that:

Plaintiff does not allege that Defendants’ alleged misrepresentation affected the [products’] price, nor does she allege that she or any of the putative class members suffered from cancer or other health problems as a result of using the [products]. Their alleged injury was purely economic: the purchase price of the [products]. Accordingly, Plaintiff merely attempts to plead “deception as both act and injury”—a theory time and again rejected by New York courts.

*Id.* (internal citations omitted).

Plaintiff’s claims here fail for the same reason. Plaintiff’s theory of injury is substantively identical to that of the plaintiffs in *Zottola* and the other cases cited above: “Plaintiff would not have purchased the Product had she known that the Challenged Representation as false” (ECF 23, ¶ 9); “Plaintiff and similarly situated consumers would not have purchased the Products, or would not have purchased the Products for as great a price, if they had known that the Challenged Representation was false” (ECF 23, ¶ 44); “Plaintiff spent money in the transaction that she otherwise would not have spent had she known the truth about Defendant’s advertising claims” (ECF 23, ¶¶ 64, 73).

Just like the plaintiff in *Zottola*, Plaintiff here does not allege that the “Reef Friendly” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate” claim

on the label affected the product's price. *See Zottola*, 2021 WL 4460563, at \*3. Plaintiff's notion that she would not have purchased the products for as great a price "amounts to nothing more than the conclusory claim that, as a result of [Defendant's] deceptive conduct, Plaintiff[] 'paid more than [she was] subjectively willing to otherwise pay.'" *See Irvine*, 2017 WL 4326538, at \*4 (quoting *Belcastro v. Burberry Ltd.*, No. 16-CV-1080 (VEC), 2017 WL 744596, at \*5 (S.D.N.Y. Feb. 23, 2017)). The only instance in which Plaintiff comes close to making any type of "price premium" allegation is in FAC ¶ 37, where Plaintiff claims generally that "manufacturers, such as Defendant, 'greenwash' their products by labeling them with environmentally and eco-friendly claims, such as the Challenged Representation, to charge consumers a premium for reef-friendly products[.]" Such a general allegation about what manufacturers *like* Defendant or products *like* those at issue in this case is not enough to adequately allege any injury under a price premium theory. Moreover, Plaintiff's allegation is wholly conclusory and offers absolutely no underlying facts in support. *See Rodriguez v. Hanesbrands Inc.*, No. 17-CV-1612 (DLI), 2018 WL 2078116, at \*5 (E.D.N.Y. Feb. 20, 2018), *report and recommendation adopted*, No. 17CV1612DLIRLM, 2018 WL 1686105 (E.D.N.Y. Mar. 30, 2018) (plaintiffs adequately alleged an injury under a price premium theory by "providing a table that compares the prices paid by plaintiffs with those of comparable [products] sold at" the locations plaintiffs purchased the products).

Plaintiff thus lacks standing under GBL §§ 349 and 350. Plaintiff is attempting to plead deception as both act and injury and, as this Court and numerous others have recognized, such an alleged injury is not cognizable. Plaintiff's claims should be dismissed.

#### IV. PLAINTIFF’S BREACH OF WARRANTY CLAIMS FAIL

Plaintiff’s breach of warranty claims<sup>2</sup> should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) for three independent reasons.<sup>3</sup> First, Plaintiff lacks the requisite privity. Second, Plaintiff did not give the requisite notice to Defendant before filing suit. Finally, and specific to the breach of express warranty claim, Plaintiff cannot allege reliance on and breach of a purported warranty based on the “Reef Friendly\*” claim while simultaneously ignoring the clarifying language that reads “\*Hawaii Compliant: No Oxybenzone or Octinoxate.”

##### A. Plaintiff Lacks Privity of Contract with Defendant

Under New York law, privity of contract between Plaintiff and Defendant is required to state a claim for breach of express and implied warranty. *Colpitts*, 527 F. Supp. 3d at 589. As this Court recognized in *Klausner v. Annie’s, Inc.*, absent allegations of personal injury, privity is “an essential element” to state a claim for breach of an express warranty and breach of the implied warranties of merchantability and fitness for a particular purpose. No. 20-CV-08467 (PMH), 2022 WL 204356, at \*6-7 (S.D.N.Y. Jan. 24, 2022). In *Klausner*, the plaintiff alleged she purchased fruit snacks from stores like ShopRite, but did not allege she purchased fruit snacks directly from the defendant. *Id.* Additionally, the plaintiff did not plead personal injury – “her alleged injury [was], instead, purely economic.” *Id.* Accordingly, this Court dismissed the plaintiff’s breach of express and implied warranty claims. *Id.*; see also *Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 290 (S.D.N.Y. 2014) (dismissing breach of express warranty claim because plaintiffs

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<sup>2</sup> In her FAC, Plaintiff alleged a breach of implied warranty, in addition to breach of express warranty. See ECF 23 at ¶ 78. In her Pre-Motion Letter, Plaintiff conceded her breach of implied warranty claim. See ECF 25 at n.2. However, during the pre-motion conference, Plaintiff’s counsel waived on whether Plaintiff did in fact concede her breach of implied warranty claim. Because of said uncertainty, Defendant addresses implied warranty herein.

<sup>3</sup> Plaintiff’s breach of warranty claims are the only claim Plaintiff purports to bring on behalf of a nationwide class. See ECF 23 at ¶¶ 75-81. Accordingly, the dismissal of Plaintiff’s warranty claims will dispose of the nationwide class.

failed to allege privity with defendants); *Ebin v. Kangadis Food Inc.*, No. 13 CIV. 2311 JSR, 2013 WL 6504547, at \*6 (S.D.N.Y. Dec. 11, 2013).

Here, Plaintiff is admittedly not in privity with Defendant. ECF 23 at ¶ 9 (Plaintiff alleges she purchased the Hawaiian Tropic® product from “a Walmart Store in Middletown, New York, in July 2021.”). Moreover, Plaintiff’s alleged injury is purely economic. Accordingly, Plaintiff’s warranty claims – and the nationwide class Plaintiff purports to represent – require dismissal.

#### **B. Plaintiff Did Not Give Defendant the Required Pre-Suit Notice**

The New York U.C.C. requires that a “buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach.” N.Y. U.C.C. Law § 2-607(3)(a). *See also Colpitts*, 527 F. Supp. 3d at 589 (“[u]nder New York law, a plaintiff must also give notice of the breach to the seller before he can recover under an express warranty claim” and “[plaintiff’s] breach of implied warranty claim also fails for lack of pre-suit notice”). The requirement is “intended to ‘open[] the way for normal settlement through negotiation.” *Singleton v. Fifth Generation, Inc.*, No. 515CV474BKSTWD, 2016 WL 406295, at \*12 (N.D.N.Y. Jan. 12, 2016) (quoting N.Y. U.C.C. Law § 2-607 (Official Comment 4)). The failure to satisfy the pre-suit notice requirement is fatal to breach of warranty claims and warrants dismissal with prejudice. *Colpitts*, 527 F. Supp. 3d at 590.

Plaintiff failed to provide pre-litigation notice. While Plaintiff pleads “Pre-litigation Notice,” *see* ECF 23 at ¶ 80; Plaintiff concedes that Defendant did not receive notice until October 12, 2021 – which was not pre-suit. *See* ECF 25 at 3; ECF 1 (filed on October 7, 2021). Not only did Plaintiff utterly fail to comply with the pre-suit notice requirement, Plaintiff falsely alleges that her counsel “sent Defendant a notice letter via certified mail, return receipt requested. . . . The form, content, and delivery of the Notice Letter complied with UCC section 2-607” and misleadingly implies her letter was timely because it was purportedly sent “prior to the filing of

this complaint, on or about October 4, 2021.” *See* ECF 23 at ¶ 80. The requirement is not that Plaintiff merely *send* the letter prior to filing her Complaint. She must give Defendant notice prior to filing her Complaint, *i.e.*, Defendant must actually *receive* the “pre-suit” notice letter before the lawsuit is filed. To permit otherwise would defeat the fundamental purpose of the pre-suit notice requirement, which is to “open[] the way for normal settlement through negotiation.” *Singleton*, 2016 WL 406295, at \*12. Because Plaintiff fails to plausibly plead she provided Defendant with pre-suit notice, dismissal is warranted.

### **C. Plaintiff Cannot Ignore Half of the Claim on the Label**

Defendant cannot breach an express warranty that Defendant did not promise to make. “[A] breach of express warranty claim must allege: (1) the existence of a material statement amounting to a warranty, (2) the buyer’s reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the buyer caused by the breach.” *Colpitts*, 527 F. Supp. 3d at 589 (internal quotations omitted). “This requires a plaintiff to plead the ‘exact terms of the warranty’ as well as the plaintiff’s reliance on those terms as a basis for the bargain.” *O’Neil v. Argon Medical Devices, Inc.*, No. 3:17-CV-640, 2020 WL 1149904, at \*7 (N.D.N.Y. Feb. 12, 2020). *See also Hingos v. W.L. Gore & Assoc.*, No. 3:16-CV-969, 2017 WL 3309095 \*6 (N.D.N.Y. Jan. 27, 2017) (“a plaintiff must allege . . . the exact terms of the warranty”).

As evident from the actual statements (“Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” or “\*No Oxybenzone or Octinoxate”) that were the basis of the bargain, Defendant did not make an express warranty that the products only include ingredients that do not cause harm to and/or kill coral reefs. Plaintiff cannot allege that she reasonably relied on *some terms* of the warranty, she must allege that she reasonably relied on the *exact terms* of the warranty. *See O’Neil*, 2020 WL 1149904 at \*7; *Hingos*, 2017 WL 3309095 at \*6. The only potential warranty here stems from the “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or



Octinoxate” statement on the product label. And if Plaintiff had relied on the complete and exact terms of “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” then no breach would exist. Plaintiff does not allege the products contain Oxybenzone or Octinoxate.

**V. PLAINTIFF’S CLAIMS ARE SUBJECT TO THE FDA’S PRIMARY JURISDICTION.**

Pursuant to Fed. R. Civ. P. 12(b)(6)<sup>4</sup> Plaintiff’s claims should be dismissed because the doctrine of primary jurisdiction permits a court to dismiss or stay a party’s claim that falls within the jurisdiction of a federal agency. As evidenced by the FDA’s regulation of the products and the FDA’s current considerations of the environmental impacts of over-the-counter (“OTC”) sunscreens, dismissal is warranted.

**A. The FDA is Actively Evaluating the Impact of OTC Sunscreens On Coral Reefs.**

The Food Drug and Cosmetic Act (“FDCA”) authorizes the FDA to regulate the ingredients and labeling of nonprescription, OTC drugs, including the sunscreen products at issue here. *See* 21 U.S.C. §§ 351, 352.21; 21 C.F.R. § 201, *et seq.* The FDA is currently in the process of promulgating new OTC sunscreen regulations that cover sixteen sunscreen active ingredients, including the regulation of avobenzone, homosalate, octisalate, and octocrylene, the four ingredients in the products that Plaintiff claims harm coral reefs, and oxybenzone and octinoxate, the two ingredients excluded from Hawaiian Tropic® products. *See* 86 Fed. Reg. 53,322 (Sept. 27, 2021).

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<sup>4</sup> Although primary jurisdiction is considered a 12(b)(6) argument, it is sufficiently akin to a 12(b)(1) argument that matters outside the pleadings are properly considered. *Canale v. Colgate-Palmolive*, 258 F.Supp.3d 312, 324 n. 11 (S.D.N.Y. 2017) (“While it thus appears [a primary jurisdiction] argument is properly analyzed under Rule 12(b)(6) . . . I find the discussion sufficiently akin to a motion under Rule 12(b)(1)—in connection with which matters outside the pleadings are properly considered . . . —so that consideration of documents beyond the four corners of the complaint is appropriate.”) (internal citations omitted).

As part of the regulatory process, the National Environmental Policy Act (“NEPA”), 42 U.S.C. § 4331 *et seq.*, requires federal agencies like the FDA to consider the potential environmental consequences of proposed actions, and establishes a formal process for agencies to follow. The FDA initiated that process on May 13, 2021, by issuing a notice of Intent to Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use (the “Environmental Impact Notice”), specifically to consider the impact of oxybenzone and octinoxate on coral reefs. *See* 86 Fed. Reg. 26,224, 26,225 (May 13, 2021). The comment period on the Environmental Impact Notice closed September 23, 2021 and the FDA is expected to issue an Environmental Impact Statement (“EIS”) addressing the impact of these ingredients on coral reefs. *See id.*

In addition, on September 8, 2021, the FDA received a citizen’s petition requesting that the FDA remove all sunscreen products containing oxybenzone, octinoxate, and octocrylene from the marketplace alleging they negatively impact waterways and coastlines, including coral reefs.<sup>5</sup> Additionally, the citizen’s petition requested that the FDA conclude “[o]nly active ingredients deemed Generally Recognized as Safe & Effective (GRASE, Category I), which include zinc oxide and titanium dioxide (mineral sunscreens), should be permitted.” *Id.* None of the ingredients relevant to this case are GRASE, Category I, thus the citizen’s petition effectively requests a ban on all of the ingredients relevant here. On March 7, 2022, the FDA sent an interim response to the citizen’s petition stating: “FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. . . . We will

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<sup>5</sup> *Citizen Petition from President Island Green Living Association Personal Care Products Toxicologist*, (Sept. 8, 2021), <https://www.regulations.gov/document/FDA-2021-P-0985-0001>.

respond to your petition as soon as we have reached a decision on your requests.”<sup>6</sup> Defendant disputes that any of these beneficial sunscreen filters are harmful to coral reefs in the extremely small quantities found in the oceans,<sup>7</sup> as opposed to forcibly high concentrations in a laboratory, but Congress has determined that the FDA should make this evaluation (subject to judicial review).

**B. Plaintiff’s Claims Are Subject to The FDA’s Primary Jurisdiction.**

Federal law bars Plaintiff’s claims, as they are subject to the primary jurisdiction of the FDA. The primary jurisdiction doctrine ensures the proper working relationship between federal agencies and courts. *See United States v. W. Pac. R. Co.*, 352 U.S. 59, 62 (1956); *Far E. Conf. v. United States*, 342 U.S. 570, 575 (1952). The doctrine “applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.” *Western Pac. R. Co.*, 352 U.S. at 64. The relevant inquiry is whether a case raises issues of fact not within the conventional experience of judges, but within the purview of an agency’s responsibilities. *Ellis v. Trib. Television Co.*, 443 F.3d 71, 82 (2d Cir. 2006). “Courts should be especially solicitous in deferring to agencies that are simultaneously contemplating the same issues.” *Id.* at 88.

In assessing whether to defer a decision to an agency, Second Circuit Courts consider four factors: “(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of expertise; (2) whether the question at issue is particularly within the agency’s discretion; (3)

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<sup>6</sup> *Interim Response to Citizen Petition from FDA*, (Mar. 6, 2022), <https://www.regulations.gov/document/FDA-2021-P-0985-0019>.

<sup>7</sup> *See, e.g.,* Mitchelmore, et. al. Society of Environmental Toxicology and Chemistry, 2021, <https://setac.onlinelibrary.wiley.com/doi/10.1002/etc.4948> (“There is currently limited evidence to suggest that corals are adversely impacted by environmental exposure to UV filters.”)

whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made.” *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 324 (S.D.N.Y. 2017) (citing *Ellis v. Trib. Television Co.*, 443 F.3d 71, 82–83 (2d Cir. 2006)). Here those factors lean in favor of deferral to the FDA.

The FDA is in the process of (1) promulgating new OTC sunscreen regulations that cover all of the ingredients relevant to Plaintiff’s claim and (2) reviewing and responding to a citizen’s petition that asks for all chemical UV filters, which includes all ingredients at issue in this case, to be banned. *See supra* § V.A. All of the factors in favor of primary jurisdiction are present.

First, the issue of which ingredients should be included/excluded from sunscreens for the purpose of preserving coral reefs requires both technical scientific considerations and policy considerations within the FDA’s area of expertise. Plaintiff claims the “Reef Friendly\*” “\*Hawaii Compliant: No Oxybenzone or Octinoxate” claim on the label is misleading, but Plaintiff’s claims can only survive if the “harmful ingredients” are in fact, harmful to reefs. The fact that the FDA is currently performing environmental studies on the effects that various chemical ingredients have on coral reefs weighs in favor of yielding to the FDA’s technical and policy considerations as the studies are within the agency’s particular field of expertise.

Second, by enacting NEPA, Congress created a process for agencies to evaluate the environmental impact of their actions and the FDA exercises comprehensive authority to regulate the labeling of OTC sunscreen products. The FDA’s Proposed Final Order will cover all the ingredients relevant to this action—avobenzone, homosalate, octisalate, octocrylene, oxybenzone, and octinoxate. In conjunction with that action, the FDA issued the Environmental Impact Notice stating that the FDA will examine the impacts of oxybenzone and octinoxate on coral reefs. NEPA requires agencies to include in every recommendation or report on actions that “significantly

affect[] the quality of the human environment, a detailed statement [on] the environmental impact of the proposed action.” 42 U.S.C. § 4332. “Human environment” means “comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment.” 40 C.F.R. § 1508.1. FDA regulations require the FDA to undertake NEPA environmental analysis when circumstances “indicate that the specific proposed action may significantly affect the quality of the human environment,” including actions where data establish that the expected environmental exposure creates potential for serious harm, or where the action is likely to adversely impact an endangered species. 21 C.F.R. § 25.21. The question of whether the ingredients at issue in this case are harmful to coral reefs is within the FDA’s discretion, discretion on which the FDA is currently acting.

Third, as detailed in above, the FDA has determined its environmental impact analysis pursuant to NEPA is only required for two of the sixteen ingredients subject to the Proposed Final Order—the two ingredients that the label specifically indicate it does not contain. The FDA did not include any of the other ingredients in the Notice, including those that Plaintiff complains of, indicating that FDA does not view the impacts of any of the other fourteen ingredients on coral reefs to even rise to the level of requiring further investigation. Moreover, the citizen’s petition currently pending before the FDA will require the FDA to determine (1) whether the active ingredients oxybenzone, octinoxate, and octocrylene should be moved to GRASE Category II (meaning such ingredients are not recognized as safe and effective for use in sunscreens and (2) whether “[o]nly active ingredients deemed [GRASE Category I], which include zinc oxide and titanium dioxide (mineral sunscreens) should be permitted.”<sup>8</sup> The citizen’s petition essentially

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<sup>8</sup> *Citizen Petition from President Island Green Living Association Personal Care Products Toxicologist*, (Sept. 8, 2021), <https://www.regulations.gov/document/FDA-2021-P-0985-0001>.

asks the FDA to ban all UV chemical barriers to harmful sun rays including each of the active ingredients at issue in this case, none of which are currently GRASE Category I. The FDA's response to the citizen's petition will no doubt impact this case. Should the FDA deem all active ingredients at issue here, safe, effective, and not an environmental risk, allowing this case to persist would create a substantial danger of inconsistent rulings.

Finally, the FDA is conducting an ongoing investigation into sunscreen ingredients as indicated by its Environmental Impact Notice and is currently engaging in an "extensive review and analysis" into the issues raised in the citizen's petition including all the active ingredients identified in this case. The Court should defer to the FDA's discretion, ongoing technical review, and expertise and stay Plaintiff's FAC until the FDA issues the EIS and responds to the citizen's petition or, alternatively, dismiss the case. Failing to wait could result in a ruling that contradicts the FDA's determination on the impact of these ingredients on coral reefs.

### **CONCLUSION**

For the reasons set forth above, Plaintiff's claims should be dismissed with prejudice. The numerous deficiencies in Plaintiff's FAC cannot be remedied by a second amended pleading. Accordingly, the Court should dismiss this action.

Date: May 3, 2022

STINSON LLP

Kieran Corcoran (KC4935)  
Telephone 212.763.8491  
Fax: 917.439.4993  
Email: kieran.corcoran@stinson.com  
1325 Avenue of the Americas, 27<sup>th</sup> Floor  
New York, NY 10019

S/ Thomas H. Davis  
Thomas H. Davis (*admitted pro hac vice*)  
Telephone 816.691.3439  
Fax: 816.412.1100  
Email: thomas.davis@stinson.com  
Megan McCurdy (*admitted pro hac vice*)  
Telephone 816.691.2649  
Fax: 816.412.9733  
Email: megan.mccurdy@stinson.com  
Logan T. Fancher (*admitted pro hac vice*)  
Telephone 816.691.2692  
Fax: 816.412.1132  
Email: logan.fancher@stinson.com  
1201 Walnut, Suite 2900  
Kansas City, MO 64106

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on the 3rd day of May, 2022, the above and foregoing was served via electronic mail as follows:

BURSOR & FISHER, P.A.

Neal J. Deckant  
Brittany S. Scott  
1990 North California Blvd., Suite 940  
Walnut Creek, CA 94596  
Telephone: (925) 300-4455  
Facsimile: (925) 407-2700  
Email: [ndeckant@bursor.com](mailto:ndeckant@bursor.com)  
[bscott@bursor.com](mailto:bscott@bursor.com)

CLARKSON LAW FIRM  
Katherine A. Bruce  
9255 Sunset Boulevard, Suite 804  
Los Angeles, CA 90069  
Telephone: 213-788-4050  
Email: [kbruce@clarksonlawfirm.com](mailto:kbruce@clarksonlawfirm.com)

Ryan Clarkson  
22525 Pacific Coast Highway  
Malibu, CA 90265  
Telephone: 213-788-4050  
Email: [rclarkson@clarkwsonlawfirm.com](mailto:rclarkson@clarkwsonlawfirm.com)

ATTORNEYS FOR PLAINTIFF

S/ Thomas H. Davis  
ATTORNEY FOR DEFENDANT